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10/646,639

08/22/2003

Thomas J. Fogarty

ARB-9003

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

07/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/646,639 | Applicant(s) FOGARTY ET AL. | |
| | Examiner Paul B. Prebilic | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 3-5,35,36,42-44,46-50,55 and 97-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9,10,16,21,29-32,34,37,41,51-53,56,74,96,113,114 and 116-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07/2008</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,9,10,16,21,29-32,34-37,41-44,46-53, 55-56, 74,96-107,113,114 and 116-130.

Election/Restrictions

Claims 3-5, 35, 36, 42-44, 46-50, 55, and 97-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 22, 2006.

Information Disclosure Statement

The information disclosure statement filed November 7, 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. For this reason, the French patent has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 96, 113, 114, 119-123, 125, 126, and 128-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 6,241,765) in view of Duncan (US 4,548,202) or Anderson et al (US 6,589,279).

Griffin meets the claim language wherein:

Art Unit: 3774

- the annular body as claimed is the shoulder (57) or ring (29) of Griffin; see Figures 7, 4, and 3 as well as column 5, lines 19-55;
- the receptacles as claimed are the openings (96) and the shoulder portions therearound;
- the shelf as claimed is the surface (82);
- the slope as claimed is the inner surface of the opening (96);
- the attachment devices as claimed are the pins (91);
- the detents as claimed are the barbs (94) and/or heads (92).

Griffin also discloses elongate attachment devices having sufficient length such that the annular body can be parachuted down to the implantation site because this language does not clearly require a particular length and is considered read on by the fasteners of Griffin. Griffin explains that any suitable fastening system of pins and staples can be utilized therewith; see column 5, lines 31-50. However, Griffin fails to disclose detents spaced along the length of the attachment device intermediate the opposite ends as claimed. Duncan (see Figures 1 to 4 and columns 5 and 6) or Anderson (see Figures 2 to 6) teaches that it was known to make elongate attachment devices that have detents along the length thereof within the tissue fastener art. Therefore, it is the Examiner's position that it would have been obvious to utilize or substitute the fasteners of Griffin for the fasteners of Duncan or Anderson because such a substitution would provide a predictable result; see MPEP 2143, criteria B.

Regarding claim 113 and similarly worded claims, the heart valve as claimed is the valve body (14) of Griffin, the gasket as claimed is the ring (29), and the sewing ring

Art Unit: 3774

or skirt as claimed is the shoulder (57). The inner radius is the portion of the opening (96) closest to the central axis of the valve, the outer radius as claimed is the farthest portion of the opening (96) from the central axis, and the gasket radius is the inner radius of the valve ring (29).

Claims 1, 2, 9, 10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 116-118, 124, and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al (US 6,241,765) in view of Colvin et al (US 6,066,160) and Duncan (US 4,548,202). Griffin meets the claim language as explained in the Section 102 rejection *supra* but fails to disclose teeth in each receptacle and/or separate can elements as claimed. However, Colvin teaches that it was known to make separate receptacles (e.g. devices (12) or (70) of Colvin) that ratchet sutures thereto in the implantation of heart valves; see Figure 4 and column 9, line 59 et seq. Griffin also discloses elongate attachment devices having sufficient length such that the annular body can be parachuted down to the implantation site because this language does not clearly require a particular length and is considered read on by the fasteners of Griffin or those fasteners substituted therefor by the rejection.

Griffin explains that any suitable fastening system of pins and staples can be utilized therewith; see column 5, lines 31-50. Duncan teaches that it was known to the tissue fastening art to utilize fasteners that have teeth on both the staple legs and in the receptacles; see the abstract, Figures 1 to 4 and columns 5 and 6.

Therefore, it is the Examiner's position that it would have been obvious to utilize separate receptacles, as taught by Colvin, that include teeth both on the pin and in the

receptacle opening, as taught by Duncan, in order to provide wider ranges of tissue size fastening capabilities to the Griffin device.

Response to Arguments

Applicant's arguments filed December 19, 2008 have been fully considered but they are not persuasive. The Applicant argues that Griffin teaches away from parachuting by teaching away from suturing. However, the Examiner asserts that Griffin does not teach away from parachuting or suturing merely because Griffin says that it takes significant skill and time to suture a heart valve with a suture ring; see column 1, lines 31-40 of Griffin. In other words, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Furthermore, parachuting has an imprecise scope such that it has been interpreted broadly by the Examiner to encompass structures that are the length of pins. This is due to the fact that the term does not require any particular length or any particular distance. Rather, it is a term of intended use and requires only a slight movement of the fastener into the receptacle to be met.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/646,639
Art Unit: 3774

Page 7

/Paul Prebilio/
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Primary Examiner
Art Unit 3774